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Glen Belvis, Reg. No. 31,735

Name of applicant, assignee or Registered Representative

Signature

Date of Signature

Our Case No. 659-764 K-C Ref. No. 14,645

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re Application of: |) |
|---|-----------------------------------|
| Gary L. SHANKLIN, et al. |)) |
| Serial No. 09/753,136 |) Examiner: Sharon L. Howard) |
| Filing Date: December 29, 2000 |) Art Unit: 1615) |
| For: ANTI-VIRAL LOTION TISSUE AND METHODS FOR MAKING AND USING THE SAME |))) |

APPEAL BRIEF

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Appeal is in response to the Final Office Action mailed May 17, 2004, rejecting Claims 1-7, 10-20 and 25-30, all the claims pending herein.¹

¹ Appellant filed a Notice of Appeal on November 12, 2004, along with a Petition for an Extension of Time of three months. Appellant files herewith a Petition for an Extension of Time of one month. Accordingly, the present Appeal Brief is timely filed.

(1) REAL PARTY IN INTEREST

Kimberly-Clark Worldwide, Inc. is the real party of interest in this Appeal pursuant to an assignment by the inventors.

(2) RELATED APPEALS AND INTERFERENCES

The undersigned, Glen Belvis, is not aware of any other appeals or interferences that would directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

(3) STATUS OF CLAIMS

The status of the claims is as follows:

Claims 23 and 24 are canceled.

Claims 8-9, 21-22 and 31-35 are withdrawn from further consideration.

Claims 1-7, 10-20 and 25-30 are currently pending and appealed herein. A copy of the pending claims is attached as Appendix A.

(4) STATUS OF AMENDMENTS

Appellants have not filed any Amendments in response to the Final Office Action of May 17, 2004.

(5) SUMMARY OF INVENTION

In an embodiment of the invention, there is provided a non-irritating anti-viral lotioned tissue product having applied to at least one surface thereof (Page 10, lines 4-

8) an anti-viral lotion composition comprising a virucidal effective amount of at least one anti-viral organic acid (Page 4, line 18 – page 5, line 9); and a topical delivery system including at least one polyester (Page 5, lines 10-28).

In another embodiment of the invention, there is provided a lotioned tissue product having applied to at least one surface thereof (Page 10, lines 4-8) an anti-viral lotion composition comprising about 1% to about 25% of at least one anti-viral organic acid (Page 5, lines 1-2); about 5% to about 25% of an emollient indicating at least one polyester (Page 5, lines 10-28); and a cationic surfactant (Page 6, lines 1-17).

In yet another embodiment of the invention, there is provided a non-irritating, anti-viral lotion composition comprising a virucidal effective amount of at least one anti-viral organic acid (Page 4, line 18 – page 5, line 9); a cationic surfactant (Page 6, lines 1-17); and a topical delivery system including at least one polyester (Page 5, lines 10-28).

In yet another embodiment of the invention, there is provided an anti-viral lotion composition comprising about 1% to about 25% of at least one anti-viral organic acid (Page 5, lines 1-2); about 5% to about 25% of an emollient indicating at least one polyester (Page 5, lines 10-28); and a cationic surfactant (Page 6, lines 1-17).

In yet another embodiment of the invention, there is provided a method of inhibiting the transfer of a viral infection comprising providing anti-viral lotion tissue product having applied to at least one surface thereof an anti-viral lotion composition (Page 10, lines 4-8) comprising a virucidal effective amount of at least one anti-viral organic acid (Page 4, line 18 – page 5, line 9) and a topical delivery system including at least one polyester (Page 5, lines 10-28); contacting a fluid containing at least one virus

with said anti-viral tissue product (Page 4, lines 3-4); and absorbing said fluid within said absorbent article to contact the fluid with said anti-viral lotion composition (Page 4, lines 4-5).

(6) ISSUES

There is one issue presented for review:

The issue is whether claims 1-7, 10-20 and 25-30 are obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 5,989,527 to Siegfried et al. in view of U.S. Patent No. 5,871,763 to Luu et al.

(7) GROUPING OF CLAIMS

For the purpose of this appeal the claims stand or fall together.²

(8) ARGUMENT

1. Description of the present invention

Appellants have developed an anti-viral lotion that is effective at killing viruses, yet allows less irritation to a user's skin than conventional lotions containing anti-viral agents. It has been discovered that the combination of an anti-viral effective amount of one or more anti-viral organic acids can be combined with an emollient or topical delivery system including at least one polyester. This topical delivery system allows the incorporation of the anti-viral organic acids into the lotion formulation, controls their

² It is noted for the record, however, that, separate from the issues in this appeal, independent claims 1, 11, 14, 25 and 28 are all mutually distinct, since each claim contains a combination of claim elements not found in the other independent claims.

delivery, and maintains them in the stratum corneum. This reduces the amount of anti-viral organic acid necessary for efficacy, and thereby reduces the potential for irritation. The anti-viral lotion can be applied to one or more surfaces of a tissue product to provide an anti-viral lotion tissue. The anti-viral lotion tissue can be used to prevent the spread of a viral infection by contacting the tissue product to a body part, such that a fluid containing at least one virus, such as nasal discharge, is absorbed into the tissue.

2. Claims 1-7, 10-20 and 25-30 are nonobvious over U.S. Patent No. 5,989,527 to Siegfried et al. in view of U.S. Patent No. 5,871,763 to Luu et al.

Claims 1-7, 10-20 and 25-30 were finally rejected in the Office Action of May 17, 2004, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,989,527 to Siegfried et al. ("Siegfried") in view of U.S. Patent No. 5,871,763 to Luu et al ("Luu").

The Examiner in the August 12, 2003, Office Action asserted (1) that Siegfried teaches lotion compositions containing a polyester, an organic acid such as citric acid and malic acid, and other ingredients such as emulsifiers and emollients and (2) Luu teaches a tissue product treated with a lotion composition, where the lotion composition includes a cationic surfactant, an emollient and an anti-viral agent. The Examiner further asserted that the combination of the tissue product of Luu with the lotion of Siegfried would provide the tissue products and lotions as claimed by Appellants. The Examiner stated that the lotion compositions of Siegfried and Luu were useful for the same purpose, and that their combination would provide a third composition useful for the same purpose, specifically for a lotion that was non-greasy and smooth feeling.

The Appellants in the February 4, 2004, Office Action Response noted that the

Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. § 103(a) as a basis for rejection of these claims. The Examiner has not provided an adequate suggestion or motivation to combine the teachings of the references to provide the tissue products or lotions as claimed. The Appellants explained that there is no motivation to combine the applied references because the lotions described in the references are not intended for the same purpose. The Appellants also explained that there is no motivation to combine because the teachings provided by the references would be viewed by those of skill in the art as incompatible.

Regrettably, the Examiner in the May 17, 2004, Final Office Action simply repeated the rejection put forth in the August 12, 2003, Office Action that the combination would provide a third composition useful for the same purpose, but without addressing the arguments presented by the Appellants that the lotions disclosed in the applied references are clearly incompatible. Moreover, the Examiner asserted that there is motivation to combine the references because:

... the references both teach a lotion composition comprising an organic acid. The motivation for using the Luu et al. reference is that Luu et al. teaches a lotionized tissue, which acts to maintain the proper skin moisture/vapor balance, which users find soothing to irritated or damaged skin, and which kills bacteria and fungi commonly found on skin, thereby providing an enhanced cleaning and deodorizing benefit. [August 12, 2003, Office Action, at page 4]

Appellant traverses this rejection.

First, the Examiner has not provided a proper suggestion or motivation to combine the applied references. The rejection's reliance on *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980) is misplaced. Even though *Kerkhoven* states that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very

same purpose, the rejection fails to address the **intended purpose** of the compositions of Siegfried and Luu. Rather, the rejection focuses on the **common components** of the compositions taught by the references. ("Both references teach a lotion composition comprising an organic acid and an emollient."³; "there is motivation to combine the Siegfried and Luu references, because the references both teach a lotion composition comprising an organic acid."⁴).

Appellants have previously discussed the purpose of the lotion of Luu in the Response to Office Action filed July 11, 2002, and in the Appellants' Brief filed April 30, 2003. As noted on pages 4-5 of the Office Action, the primary objective of Luu is to provide a lotion that has a "non-greasy feeling" [col. 3, lines 48-51]. In contrast, the primary objective of Siegfried is to provide topical delivery of an active ingredient, which is "a chemical exfoliating agent, sunless tanning agent, skin lightening agent or an insect repellent" [col. 3, lines 32-36]. Thus, Luu and Siegried are not taught to be useful for the same purpose.

Second, one of skilled in the art would not be motivated to combine the teachings of Siegfried with Luu because the teaching of Siegfried is incompatible with the teaching of Luu. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (CCPA 1959); MPEP § 4143.01. As noted above, the primary objective of Luu is to provide a lotion that has a "non-greasy feeling" [col. 3, lines 48-

³ Office Action of May 17, 2004, page 3.

⁴ Office Action of May 17, 2004, page 4

51]. This is accomplished by preparing the lotion from relatively higher melting point components that are <u>solids</u> on the tissue product, and that may melt and then resolidify when transferred from the tissue to the user's skin [col. 3, lines 61-65]. In accordance with these teachings, the lotion of Luu preferably includes a high concentration (25% - 90%) of a retention/release agent having a melting onset between 30°C and 65°C [col. 5, lines 55-57 and col. 6, lines 50-53]. The retention/release agent may be a polymer "having an appropriate melting point range" [col. 6, lines 64-65].

In contrast, the lotion of Siegfried includes a low concentration of polyester delivery aid, preferably from 0.5 weight percent (wt%) to 25 wt% [col. 13, lines 12-16]. This concentration range is disclosed with reference to the exfoliating lotion composition of Siegfried, which is the only composition disclosed as including an organic acid active ingredient [col. 10, line 44 – col. 1, line 36]. Referring to Example 1 [col. 18, line 10 – col. 21, line 7], in the exemplary exfoliating lotion compositions, the concentration of polyester delivery aid is only 5 wt%, and the concentration of the entire oil phase (part B) is only 10.5 wt%, much lower than the preferred concentrations of the retention/release agents taught by Luu.

Moreover, the polyesters of Siegfried are <u>liquid</u> at room temperature. Attached at Appendix B, which was originally submitted with the Response of February 4, 2004, is a Material Safety Data Sheet (MSDS) for trimethylpentanediol/adipic acid copolymer, where the copolymer is in diol form. Attached at Appendix C, which also was originally submitted with the Response of February 4, 2004, is an MSDS for trimethylpentanediol/adipic acid copolymer, where the copolymer is in fatty alkyl capped form. These polyesters are indexed to the Siegfried reference on page 1, section 3 of

each MSDS. In the physical and chemical properties listed on page 3, section 9 of each MSDS, the melting point of these polyesters is reported as less than 25°C. The polyesters of Siegfried are thus liquids at room temperature and do not have the "appropriate melting range" of 30°C and 65°C as specified by Luu.

Consequently, the use of liquid polyester delivery aids at low concentrations according to Siegfried is incompatible with the use of high melting retention/release agents at high concentrations as taught by Luu. Accordingly, since the pending claims are nonobvious under 35 U.S.C. § 103(a) over Siegfried in view of Luu, Appellants respectfully submit that the rejection should be withdrawn and the claims should be allowed.

(9) CONCLUSION

In summary, Appellants respectively submit that claims 1-7, 10-20 and 25-30 are improperly rejected under 35 U.S.C. § 103(a), because the use of liquid polyester delivery aids at low concentrations according to Siegfried is incompatible with the use of high melting retention/release agents at high concentrations according to Luu. Consequently, Appellants respectfully submit that the rejection should be withdrawn and the claims should be allowed.

Respectfully submitted,

Glén Belvis

Registration No. 31,735 Attorney for Appellants

BRINKS HOFER GILSON & LIONE P.O. Box 10395 Chicago, Illinois 60610 (312) 321-4200

Dated: February 7, 2005

IX. APPENDIX A

- 1. A non-irritating anti-viral lotioned tissue product having applied to at least one surface thereof an anti-viral lotion composition comprising:
 - a virucidal effective amount of at least one anti-viral organic acid; and a topical delivery system including at least one polyester.
- 2. The lotioned tissue product of claim 1, wherein said lotion composition comprises from about 1% to about 25% of said anti-viral organic acid.
- 3. The lotioned tissue product of claim 2, wherein said at least one anti-viral organic acid comprises at least one member from the group consisting of carboxylic acids having the structure R-COOH, wherein R is a C_1 - C_6 alkyl; C_1 - C_6 alkyl carboxy; C_1 - C_6 alkyl carboxyhydroxy; C_1 - C_6 alkyl carboxy halo; C_1 - C_6 alkyl carboxyhydroxy; C_1 - C_6 alkenyl; C_1 - C_6 alkenyl carboxy; C_1 - C_6 alkenyl phenyl; or substituted phenyl radical.
- 4. The lotioned tissue product of claim 3, wherein one or more hydrogen atoms of R is substituted with a functional group selected from the group consisting of halogen atoms, hydroxyl groups, amino groups, thiol groups, nitro groups, and cyano groups.
- 5. The lotioned tissue product of claim 3, wherein said at least one anti-viral acid is selected from the group consisting of citric acid, malic acid, adipic acid, glutaric acid, succinic acid, and mixtures thereof.
- 6. The lotioned tissue product of claim 2, wherein said at least one polyester comprises a hydroxyl-functional polyester diol.
- 7. The lotioned tissue product of claim 6, wherein said at least one polyester comprises trimethylpentanediol/adipic acid copolymer.

- 10. The lotioned tissue product of claim 1, wherein the lotion composition further comprises a surfactant.
- 11. A lotioned tissue product having applied to at least one surface thereof an anti-viral lotion composition comprising:

about 1 % to about 25% of at least one anti-viral organic acid; about 5% to about 25% of an emollient including at least one polyester; and

a cationic surfactant.

- 12. The lotioned tissue product of claim 11, wherein said emollient comprises at least one polyester from the group consisting of fatty alkyl capped complex polyesters, hydroxyl-functional polyester diols, and mixtures thereof.
- 13. The lotioned tissue product of claim 11, wherein said cationic surfactant comprises a quaternary ammonium compound.
 - 14. A non-irritating, anti-viral lotion composition comprising: a virucidal effective amount of at least one anti-viral organic acid; a cationic surfactant; and a topical delivery system including at least one polyester.
- 15. The lotion composition of claim 14, wherein said lotion composition comprises from about 1% to about 25% of said anti-viral organic acid.
- 16. The lotion composition of claim 15, wherein said at least one anti-viral organic acid comprises at least one member from the group consisting of carboxylic acids having the structure R-COOH, wherein R is a C₁-C₆ alkyl; C₁-C₆ alkyl carboxy; C₁-C₆ alkyl carboxyhydroxy; C₁-C₆ alkyl carboxy halo; C₁-C₆ alkylcarboxy dihydroxy; C₁-C₆ alkyl dicarboxyhydroxy; C₁-C₆ alkenyl; C₁-C₆ alkenyl carboy C₁-C₆ alkenyl phenyl; or substituted phenyl radical.

- 17. The lotion composition of claim 16, wherein one or more hydrogen atoms of R is substituted with a functional group selected from the group consisting of halogen atoms, hydroxyl groups, amino groups, thiol groups, nitro groups, and cyano groups.
- 18. The lotion composition of claim 16, wherein said at least one anti-viral acid is selected from the group consisting of citric acid, malic acid, adipic acid, glutaric acid, succinic acid, and mixtures thereof.
- 19. The lotion composition of claim 15, wherein said at least one polyester comprises a hydroxyl-functional polyester diol.
- 20. The lotion composition of claim 19, wherein said at least one polyester comprises trimethylpentanediol/adipic acid copolymer.
- 25. An anti-viral lotion composition comprising:
 about 1% to about 25% of at least one anti-viral organic acid;
 about 5% to about 25% of an emollient including at least one polyester;
 and
 a cationic surfactant.
- 26. The lotion composition of claim 25, wherein said emollient comprises at least one polyester from the group consisting of fatty alkyl capped complex polyesters, hydroxy functional polyester diols, and mixtures thereof.
- 27. The lotion composition of claim 26, wherein said cationic surfactant comprises a quaternary ammonium compound.
- 28. A method of inhibiting the transfer of a viral infection comprising:

 providing anti-viral lotion tissue product having applied to at least
 one surface thereof an anti-viral lotion composition comprising a virucidal
 effective amount of at least one anti-viral organic acid and a topical delivery
 system including at least one polyester;

contacting a fluid containing at least one virus with said anti-viral

tissue product; and

absorbing said fluid within said absorbent article to contact the fluid with said anti-viral lotion composition.

- 29. The method of claim 28, further comprising:
 transferring a portion of the lotion composition to the user of the tissue product.
- 30. The method of claim 28, wherein said at least one polyester comprises a hydroxyl-functional polyester diol.

APPENDIX B

Materials Safety Data Sheet (MSDS) for trimethylpentanediol/ adipic acid copolymer.

Available from INOLEX Chemical COMPANY, Jackson & Swanson Streets, Philadelphia, PA 19148.



MATERIAL SAFETY DATA SHEET

Product Name:

LEXOREZ° TL-8

Product Id Number:

62771

Revision Date:

06/11/2003

CHEMICAL PRODUCT AND COMPANY IDENTIFICATIONS

Product Name:

LEXOREZ° TL-8

Synonym(s):

Trimethylpentanediol / Adipic Acid Copolymer

MANUFACTURED / SUPPLIED BY: Inolex Chemical Company Jackson & Swanson Streets Philadelphia, PA 19148-3497 215-271-0800 215-271-2621 fax

PREPARER: FORMULA:

Glenn Tashjian Unspecified

2 COMPOSITION/INFORMATION ON HIGREDIENTS

Hazardous ingredients are listed if they comprise >= 1.0% by weight. "Special Hazardous Substances or Carcinogens" are listed if they comprise >= 0.1% by weight.

EXPOSURE LIMITS:

PRODUCT COMPOSITION: APPROX.

ACGIH TLV

OSHA PEL

CAS REG NO.

WGT. %

<u>TWA</u>

STEL

TWA

UNITS

NON-HAZARDOUS COMPONENTS

Hexanedioic acid, 2,2,4-Trimethyl-1,3-Pentanediol Polymer

26139-53-7

> 99 %

None

None

None

None

STEL

ppm

HAZARDS TOENT LET CATTON STORE STORE

EMERGENCY OVERVIEW:

No unusual safety, fire, or spill hazards. Consult following MSDS sections for further information. ** U.S. Patents No. 5,833,961 and 5,989,527 **

EFFECTS FROM ACUTE EXPOSURE:

INGESTION:

None known

SKIN CONTACT:

Non-Irritating to Skin.

INHALATION:

None known.

EYE CONTACT:

May cause minimal eye irritation.

MEDICAL CONDITIONS AGGRAVATED:

None known.

SUBCHRONIC (TARGET ORGAN) EFFECTS: An adverse effect with symptoms that develop slowly over a long period of time.

None known.

CHRONIC EFFECTS/CARCINOGENICITY:

Not listed in IARC, NTP or 29CFR.

LEXOREZ® TL-8

PRODUCTS/INGREDIENTS: The ingredients that are carcinogens are listed here, with specific information about their carcinogenicity.

None

PRINCIPLE ROUTES OF EXPOSURE

None known.

OTHER:

None known.

A STORY OF THE STO

INGESTION:

If swallowed, observe victim for 24 hours; seek medical attention if indicated. If vomiting occurs, keep head lower than hips to prevent aspiration.

SKIN

For skin contact, wipe away excess material with dry towel. Then wash affected areas with plenty of water, and mild soap if available, for several minutes. Get medical attention if irritation occurs.

INHALATION:

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

EYES:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

NOTE TO PHYSICIAN:

Treatment based on sound judgment of physician and individual reactions of patient.

FLASH POINT:

> 200 C

METHOD: The test method used is listed as closed cup (PMCC TCC) or open cup (COC):

FLAMMABLE LIMITS IN AIR - UPPER (%): Maximum % by volume of vapor in air above which propagation of flame does not occur on contact with a source of ignition:

N/D

SENSITIVITY TO MECHANICAL IMPACT (Y/N):

NO

SENSITIVITY TO STATIC DISCHARGE:

Sensitivity to static discharge is not expected.

EXTINGUISHING MEDIA:

Water fog, carbon dioxide, foam, dry chemical

SPECIAL FIREFIGHTING PROCEDURES:

Fire-fighters should wear self-contained breathing apparatus and full protective clothing when fighting chemical fires. Use water spray to cool nearby containers and structures exposed to fire. Containers can build up pressure if exposed to heat (fire). Fire involving large amounts of material should not be approached because individual containers may rupture abruptly causing "fireball" effect.

6. ACCIDENTAL RELEASE MEASURES

ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:

Wipe, scrape or soak up in an inert material and put in a container for disposal. Wash walking surfaces with detergent and water to reduce slipping hazard. Wear proper protective equipment as specified in the protective equipment section. Large quantity spills should be contained and pumped into drums for recovery or disposal.

HANDLING AND STORAGE

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE:

Keep container closed when not in use. Good hygienic practices should be observed. Work clothes should be washed separately at the end of each work day. Disposable clothing should be discarded with material.

NFPA:

HMIS:

LEXOREZ TL-8

0 HEALTH FLAMMABILITY

HEALTH FLAMMABILITY

据ERSTENTE

REACTIVITY

OTHER

醛

8. EXPOSURE CONTROLS/PERSONAL PROTECTION.

PPE

ENGINEERING CONTROLS:

None required.

RESPIRATORY PROTECTION EQUIPMENT:

None required under normal conditions.

PROTECTIVE GLOVES:

Use gloves as a standard industrial handling procedure.

N/A

EYE AND FACE PROTECTION:

Wear safety glasses or goggles to protect against exposure.

OTHER PROTECTIVE EQUIPMENT:

None Required VENTILATION:

No unusual ventilation required.

9. PHYSICAL AND CHEMICAL PROPERTIES 1995 See 1885

BOILING POINT 300 C

VAPOR PRESSURE 4 0.1 mm Hg

VAPOR DENSITY (AIR=1)N/D MELTING POINT 25 C

PHYSICAL STATEViscous Liquid

COLORClear, Light Amber

EVAP. RATE(BUTYL ACETATE=1) Negligible

SOLUBILITY IN WATER (20 C)INSOLUBLE

SOLUBILITY IN ORGANIC SOLVENTSN/D

10. STABILITY AND REACTIVITY

STABILITY:

STABLE

HAZARDOUS POLYMERIZATION:

WILL NOT OCCUR

HAZARDOUS THERMAL DECOMPOSITION/COMBUSTION PRODUCTS:

No unusual decomposition products known.

INCOMPATIBILITY (MATERIALS TO AVOID):

None known.

CONDITIONS TO AVOID:

None known.

TOXICOLOGECAL TOROGRATION SERVICES AND A SERVICES OF THE SERVI

ACUTE ORAL LD50 (MG/KG):

> 5,000 mg/Kg

ACUTE DERMAL LD50 (MG/KG): ACUTE INHALATION LC50 (MG/L): Unknown Unknown

AMES TEST:

Unknown

OTHER: Testing on similar products was found to be of low toxicity and low irritancy to skin and eyes. This product has not been tested on animals. Toxicity information is derived from

LEXOREZ TL-8

testing conducted on similar products. Human Patch Test, RIPT, involving 50 subjects did not indicate a potential for dermal irritation or allergic contact sensitization.

PERSONAL PROPERTY OF THE PROPE

ECOTOXICOLOGICAL INFORMATION: No data at this time CHEMICAL FATE INFORMATION: No data at this time.

DISPOSAL CONSIDERATIONS

DISPOSAL METHOD:

As local regulations may vary; all waste must be disposed/recycled/reclaimed in accordance with federal, state, and local environmental control regulations.

TRANSPORT THEORMATION

DOT SHIPPING NAME:

Non-Regulated

DOT HAZARD CLASS:

Non-Regulated

DOT LABEL(S):

NONE

UN/NA NUMBER: PLACARDS:

NONE NONE

INTERNATIONAL TRANSPORTATION CLASSIFICATIONS:

RID, European Railroad hazard class:

Not Available

IATA, International Air Transportation:

Not Available

IMDG, International Maritime Dangerous Goods: NONE

TENER TO SEE THE SECOND SE

TSCA STATUS:

All components of this product are listed on the TSCA Inventory.

SARA SECTION 302: None Found

SARA (311,312) HAZARD CLASS:

SARA (313) CHEMICALS:

THIS PRODUCT DOES NOT CONTAIN A TOXIC CHEMICAL FOR ROUTINE ANNUAL 'TOXIC CHEMICAL RELEASE REPORTING' UNDER SECTION 313 (40 CFR 372)

CERCLA HAZARDOUS SUBSTANCE: Not a listed EHS

CERCLA REPORTABLE QUANTITY: No listed reportable quantity

CALIFORNIA PROPOSITION 65: NONE

INTERNATIONAL REGULATORY STATUS:

CANADIAN (DSL) INVENTORY:

Listed on NDSL

WHMIS HAZARD CLASS:

NON-CONTROLLED

WHMIS TRADE SECRET:

None

EXPORT:

SCHDLE B/HTSUS: (Tariff Classification #) 3907.99.0000 (polyesters)

ECCN: (Export Commodity Control Number)

Not Available

EINECS INVENTORY STATUS: Excluded Polymer

LEXOREZ° TL-8

EC LABELING REQUIREMENTS:

EC REQUIRED SYMBOL(S):

None Required

EC SAFETY PHRASES:

None Required

EC RISK PHRASES:

None Required

KOREAN (ECL) INVENTORY STATUS:

Not Available

JAPANESE (MITI) INVENTORY STATUS:

ENCS No. 7-708X

AUSTRALIAN (AICS) INVENTORY STATUS: Not Available

PHILIPPINES (PICCS) INVENTORY:

Not Available

CHINESE CHEMICAL INVENTORY STATUS:

Not Available

DESCRIPTION OF THE PROPERTY OF

The following has been revised since the last issue of this MSDS: Not Available

ADDITIONAL INFORMATION: Any additional, pertinent information about this product or the MSDS itself. A legend of abbreviations used throughout the MSDS is provided in this

These data are offered in good faith as typical values and not as a product specification. No warranty, either expressed or implied, is made. The recommended handling procedures are believed to be generally applicable. However, each user should review these recommendations in the specific content of the intended use . Protected by U.S. Application Patents No.'s 5,833,961 and 5.989,527.

ASSESSMENT"

HAZARD ASSESSMENT INFORMATION:

None

SAME AS ANOTHER EXISTING PRODUCT:

N/A

OTHER INFORMATION:

None.

END OF MSDS ***

APPENDIX C

Materials Safety Data Sheet (MSDS) for trimethylpentanediol/ adipic acid / isonoanoic acid copolymer.

Available from INOLEX Chemical COMPANY, Jackson & Swanson Streets, Philadelphia, PA 19148.



MATERIAL SAFETY DATA'SHEET

Product Name:

LEXOREZ® TC-8

Product Id Number:

62772

Revision Date:

06/11/2003

COMPANY TO ENTIRE TO A CHEMICAL PRODUCT AND COMPANY TO ENTIFICATION

Product Name:

LEXOREZ® TC-8

Synonym(s):

Trimethylpentanediol / Adipic Acid / Isononanoic Acid

Copolymer

MANUFACTURED / SUPPLIED BY: Inolex Chemical Company Jackson & Swanson Streets Philadelphia, PA 19148-3497 215-271-0800 215-271-2621 fax

PREPARER:

Glenn Tashjian

FORMULA: Unspecified

2. COMPOSITION/INFORMATION ON INGREDIENTS TO A STATE OF THE STATE OF T

Hazardous ingredients are listed if they comprise >= 1.0% by weight. "Special Hazardous Substances or Carcinogens" are listed if they comprise >= 0.1% by weight.

EXPOSURE LIMITS:

PRODUCT COMPOSITION:

APPROX.

ACGIH TLV

OSHA PEL

CAS REG NO.

WGT. %

TWA

STEL

TWA

STEL

NON-HAZARDOUS COMPONENTS

Adipic acid, Trimethylpentanediol, Isononanoic acid Polymer

200512-90-9

> 98%

None

None

None

None

ppm

UNITS

HAZARDS ADENTIFICATION

EMERGENCY OVERVIEW:

No unusual safety, fire, or spill hazards. Consult following MSDS sections for further information. ** U.S. Patents No. 5,833,961 and 5,989,527 **

EFFECTS FROM ACUTE EXPOSURE:

INGESTION:

None known

SKIN CONTACT:

Non-Irritating to Skin.

INHALATION:

None known.

EYE CONTACT:

May cause minimal eye irritation.

MEDICAL CONDITIONS AGGRAVATED:

None known.

SUBCHRONIC (TARGET ORGAN) EFFECTS: An adverse effect with symptoms that develop slowly over a long period of time.

None known.

CHRONIC EFFECTS/CARCINOGENICITY:

LEXOREZ® TC-8

Not listed in IARC, NTP or 29CFR.

PRODUCTS/INGREDIENTS: The ingredients that are carcinogens are listed here, with specific information about their carcinogenicity.

None

PRINCIPLE ROUTES OF EXPOSURE:

None known.

OTHER:

None known.

FIRST AND MEASURES TO THE STATE OF THE STATE

If swallowed, observe victim for 24 hours; seek medical attention if indicated. If vomiting occurs, keep head lower than hips to prevent aspiration.

SKIN:

For skin contact, wipe away excess material with dry towel. Then wash affected areas with plenty of water, and mild soap if available, for several minutes. Get medical attention if irritation occurs.

INHALATION:

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

EYES:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

NOTE TO PHYSICIAN:

Treatment based on sound judgment of physician and individual reactions of patient.

FIRE FIGHTING MEASURES.

FLASH POINT:

> 200 C

The test method used is listed as closed cup (PMCC TCC) or open cup (COC): METHOD: COC

Maximum % by volume of vapor in air above which FLAMMABLE LIMITS IN AIR - UPPER (%): propagation of flame does not occur on contact with a source of ignition:

N/D

SENSITIVITY TO MECHANICAL IMPACT (Y/N):

NO

SENSITIVITY TO STATIC DISCHARGE:

Sensitivity to static discharge is not expected.

EXTINGUISHING MEDIA:

Water fog, carbon dioxide, foam, dry chemical SPECIAL FIREFIGHTING PROCEDURES:

Fire-fighters should wear self-contained breathing apparatus and full protective clothing when fighting chemical fires. Use water spray to cool nearby containers and structures exposed to fire. Containers can build up pressure if exposed to heat (fire). Fire involving large amounts of material should not be approached because individual containers may rupture abruptly causing "fireball" effect.

6: ACCIDENTAL RELEASE MEASURES

ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:

Wipe, scrape or soak up in an inert material and put in a container for disposal. Wash walking surfaces with detergent and water to reduce slipping hazard. Wear proper protective equipment as specified in the protective equipment section. Large quantity spills should be contained and pumped into drums for recovery or disposal.

HANDLING AND STORAGE

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE:

Keep container closed when not in use. Good hygienic practices should be observed. Work clothes should be washed separately at the end of each work day. Disposable clothing should be discarded with material.

NFPA:

HMIS:

LEXOREZ® TC-8

SMACT STY

HEALTH 0 FLAMMABILITY

HEALTH FLAMMABILITY 1

OTHER

N/A

PPE

8

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8 2 EXPOSURE CONTROLS/PERSONAL PROTECTION 2017

ENGINEERING CONTROLS:

None required.

RESPIRATORY PROTECTION EQUIPMENT:

None required under normal conditions.

PROTECTIVE GLOVES:

Use gloves as a standard industrial handling procedure.

EYE AND FACE PROTECTION:

Wear safety glasses or goggles to protect against exposure.

OTHER PROTECTIVE EQUIPMENT:

None Required

VENTILATION:

No unusual ventilation required.

PHYSICAL AND CHEMICAL PROPERTIES IN THE STATE OF THE STAT

BOILING POINT 300 C VAPOR PRESSURE d.1 mm Hg

MELTING POINT < 25 C

ODORCharacteristic Bland Odor

EVAP. RATE(BUTYL ACETATE=1)Negligible

POUNDS/GALLON (Water=8.3)8.4

DENSITY @ 25°C (WATER=1)1.01 @ 25 C

SOLUBILITY IN WATER (20 C)PARTIALLY

SOLUBILITY IN ORGANIC SOLVENTSN/D

STABILITY AND REACTIVITY

STABILITY:

STABLE

HAZARDOUS POLYMERIZATION:

WILL NOT OCCUR

HAZARDOUS THERMAL DECOMPOSITION/COMBUSTION PRODUCTS:

No unusual decomposition products known.

INCOMPATIBILITY (MATERIALS TO AVOID):

None known.

CONDITIONS TO AVOID:

None known.

TOXICOLOGICAL INCOMMITTON

ACUTE ORAL LD50 (MG/KG): > 5,000 mg/Kg

ACUTE DERMAL LD50 (MG/KG): Unknown ACUTE INHALATION LC50 (MG/L): Unknown AMES TEST: Unknown

OTHER:

Testing on similar products was found to be of low toxicity and low irritancy to skin and eyes. This product has not been tested on animals. Toxicity information is derived from

LEXOREZ® TC-8

testing conducted on similar products. Human Patch Test, RIPT, involving 50 subjects did not indicate a potential for dermal irritation or allergic contact sensitization.

TO THE REPORT OF THE PROPERTY OF THE PROPERTY

ECOTOXICOLOGICAL INFORMATION: No data at this time CHEMICAL FATE INFORMATION: No data at this time.

DISPOSATIONS OF THE ACTION OF THE PROPERTY OF

DISPOSAL METHOD:

As local regulations may vary; all waste must be disposed/recycled/reclaimed in accordance with federal, state, and local environmental control regulations.

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DOT SHIPPING NAME:

Non-Regulated

DOT HAZARD CLASS:

Non-Regulated

DOT LABEL(S):

NONE

UN/NA NUMBER:

NONE

PLACARDS:

NONE

INTERNATIONAL TRANSPORTATION CLASSIFICATIONS:

RID, European Railroad hazard class:

Not Available

Not Available

IATA, International Air Transportation: Not I IMDG, International Maritime Dangerous Goods: NONE

VIET REGULATORY INFORMATIONS

This material is manufactured for use as an additive in personal care products and is regulated under the FOOD, DRUG, and COSMETICS ACT (FDA) and is therefore, not regulated under the Toxic Substances Control Act (TSCA) ... This product or some of it's components are not on the TSCA Inventory list.

SARA SECTION 302: None Found

SARA (311,312) HAZARD CLASS:

SARA (313) CHEMICALS:

THIS PRODUCT DOES NOT CONTAIN A TOXIC CHEMICAL FOR ROUTINE ANNUAL 'TOXIC CHEMICAL RELEASE REPORTING' UNDER SECTION 313 (40 CFR 372)

CERCLA HAZARDOUS SUBSTANCE: Not a listed EHS

CERCLA REPORTABLE QUANTITY: No listed reportable quantity

CALIFORNIA PROPOSITION 65: NONE

INTERNATIONAL REGULATORY STATUS:

CANADIAN (DSL) INVENTORY:

Not Listed on DSL or NDSL

WHMIS HAZARD CLASS:

NON-CONTROLLED

WHMIS TRADE SECRET:

None

EXPORT:

SCHDLE B/HTSUS: (Tariff Classification #) 3907.99.0000 (polyesters)

LEXOREZ® TC-8

ECCN: (Export Commodity Control Number)

Not Available

EINECS INVENTORY STATUS: Not Available

EC LABELING REQUIREMENTS:

EC REQUIRED SYMBOL(S):

None Required

EC SAFETY PHRASES:

None Required

EC RISK PHRASES:

None Required

KOREAN (ECL) INVENTORY STATUS:

Not Available

JAPANESE (MITI) INVENTORY STATUS:

Not Available

AUSTRALIAN (AICS) INVENTORY STATUS: Not Available

PHILIPPINES (PICCS) INVENTORY:

Not Available

CHINESE CHEMICAL INVENTORY STATUS: Not Available

High to Other Information

The following has been revised since the last issue of this MSDS: Not Available

ADDITIONAL INFORMATION: Any additional, pertinent information about this product or the MSDS itself. A legend of abbreviations used throughout the MSDS is provided in this section.

These data are offered in good faith as typical values and not as a product specification. No warranty, either expressed or implied, is made. The recommended handling procedures are believed to be generally applicable. However, each user should review these recommendations in the specific content of the intended use . Protected by U.S. Application Patents No.'s 5,833,961 and 5.989,527.

HAZARD ASSESSMENT

HAZARD ASSESSMENT INFORMATION:

None

SAME AS ANOTHER EXISTING PRODUCT:

N/A

OTHER INFORMATION:

None.

*** END OF MSDS ***